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United States Department of Agriculture

FOOD AND DRUG ADMINISTRATION

SERVICE AND REGULATORY ANNOUNCEMENTS

Food and Drug No. 1

REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD AND DRUGS ACT

(Tenth revision)

INTRODUCTION

This publication, embodying the rules and regulations for the enforcement of the food and drugs act of June 30, 1906, as amended, supersedes the circulars on this subject previously published.

By an act of Congress making appropriations for the Department of Agriculture for the fiscal year ending June 30, 1931, and for other purposes, approved May 27, 1930, the name of the Food, Drug, and Insecticide Administration was changed to Food and Drug Administration.

These regulations are identical with those published in S. R. A., F. D. No. 1, issued October, 1927, except for the substitution of the words "Food and Drug Administration" for the words "Food, Drug, and Insecticide Administration" wherever they appear.

The text of the food and drugs act includes the amendment approved July 8, 1930.

ARTHUR M. HYDE,
Secretary of Agriculture.

WASHINGTON, D. C., *October 31, 1930.*

RULES AND REGULATIONS FOR THE ENFORCEMENT OF THE FOOD AND DRUGS ACT OF JUNE 30, 1906, AS AMENDED

Regulation 1.—Short Title of the Act

The act, "For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes," approved June 30, 1906 (34 Stat. 768), as amended by the act approved August 23, 1912 (37 Stat. 416), by the act approved March 3, 1913 (37 Stat. 732), by the act approved March 4, 1913 (37 Stat. 736), by the act approved July 24, 1919 (41 Stat. 271), by the act approved January 18, 1927 (44 Stat. 1003), by the act approved July 8, 1930 (H. R. 730), and as it may be amended hereafter, shall be known and referred to as the Federal food and drugs act.

Regulation 2.—Scope of the Act

The provisions of the act apply to foods and to drugs which have been shipped or delivered for shipment in interstate commerce, or which are exported or offered for export to foreign countries, or which are being transported in interstate commerce for sale or have been transported in interstate commerce, or which have been received from a foreign country, or which are manufactured, sold, or offered for sale in the District of Columbia, Territories of the United States, or insular possessions.

Regulation 3.—Collection of Samples and Evidence for Action Under Sections 1, 2, and 10

(Section 3)

(*a*) A sample for examination by or under the direction and supervision of the Food and Drug Administration shall be collected by—

(1) An authorized agent of the Department of Agriculture.

(2) A health, food, or drug officer of any State, Territory, city, or the District of Columbia, commissioned by the Secretary of Agriculture for this purpose.

(3) An agent of any health, food, or drug officer of any State, Territory, city, or the District of Columbia when such agent is authorized by the Secretary of Agriculture through such health, food, or drug officer commissioned by the Secretary of Agriculture for this purpose.

(*b*) Foods or drugs within the scope of sections 1, 2, and 10 of the act may be sampled wherever found. The sample shall be representative in all cases. A sample of packaged goods shall consist usually of three packages when the individual package is 4 pounds or less in weight or 2 quarts or less in volume. If the goods are in larger packages, one or two packages may suffice, depending on the character of the goods and the nature of the examination to be made. Samples whether from package or bulk goods shall, when practicable, be divided into three parts or subdivisions. All subdivisions shall be properly identified and sealed with a seal provided for the purpose by the Department of Agriculture.

(*c*) The sample shall be delivered for examination by or under the supervision of the Food and Drug Administration. Subdivisions of the sample remaining intact after analysis, except when perishable, shall be held under seal. Upon request one subdivision if available shall be delivered to the party or parties interested.

(*d*) At the time of collection all marks, brands or tags, or accompanying printed or written matter pertaining to the article sampled shall be recorded. The names of the vendor and agent from whom the sample is collected, together with the date of collection, shall also be recorded. All original invoices, bills of lading, freight bills, and other documentary evidence of shipment or sale, or copies thereof, shall be procured from the dealers, carriers, warehousemen, or other persons having possession of such documents.

(*e*) Records of common carriers and warehousemen shall be examined from time to time for the purpose of obtaining evidence of violations of the Federal food and drugs act.

(*f*) Establishments in which food or drugs are prepared in whole or in part for sale in the Territories or the District of Columbia or for transportation in interstate or foreign commerce may be inspected by any authorized agent of the Department of Agriculture.

Regulation 4.—Methods of Analysis

(Section 4)

(*a*) Drugs recognized in the United States Pharmacopœia or National Formulary for which methods of analysis have been prescribed in said Pharmacopœia or National Formulary shall be analyzed by these methods.

(*b*) All foods and such drugs as are not included in paragraph *a* of this regulation shall be analyzed by the methods prescribed by the Association of Official Agricultural Chemists, when applicable, provided, however, that any method of analysis or examination satisfactory to the Food and Drug Administration may be employed.

(*c*) All foods or drugs for which no methods of analysis have been prescribed, either in the Pharmacopœia or National Formulary or by the Association of Official Agricultural Chemists, shall be analyzed or examined by methods satisfactory to the Food and Drug Administration.

Regulation 5.—Hearings—Procedure without Hearing

(Sections 4 and 5)

(*a*) Whenever it appears that an article is adulterated or misbranded within the meaning of the act, and proceedings are contemplated under section 1 or 2, notice shall be given to the party or parties against whom prosecution is under consideration and to other interested parties, and a date shall be fixed at which such party or parties may be heard. The hearing shall be held at the office of the Food and Drug Administration most convenient to the parties cited, and shall be private and confined to questions of fact. The parties notified may present evidence, either oral or written, in person or by attorney, to show cause why the matter should not be referred for prosecution as a violation of the Federal food and drugs act.

(*b*) After a hearing is held, if it appears that the act has been violated, the Secretary of Agriculture shall report the facts to the proper United States attorney.

(*c*) The health, food, or drug officer or agent of any State, Territory, city, or the District of Columbia who shall obtain satisfactory evidence of a violation of the act may present such evidence direct to the proper United States district attorney for appropriate action under the Federal food and drugs act.

(*d*) When the procedure outlined in paragraph *c* is not followed, the health, food, or drug officer or agent of any State, Territory, city, or the District of Columbia, commissioned by the Secretary of Agriculture, who obtains satisfactory evidence of any violation of section 1 or 2 of the act shall submit such evidence to the Food and Drug Administration in order that a date for a hearing may be fixed and notice given to the proper party.

Regulation 6.—Guaranty

(Section 9)

(*a*) Any wholesaler, manufacturer, jobber, or other party residing in the United States may furnish to any dealer to whom he sells any article of food or drug a guaranty that such article is not adulterated or misbranded within the meaning of the Federal food and drugs act.

(*b*) Each guaranty to afford protection shall be signed by, and shall contain the name and address of, the wholesaler, manufacturer, jobber, dealer, or other party residing in the United States making the sale of the article or articles covered by it to the dealer, and shall be to the effect that such article or

articles are not adulterated or misbranded within the meaning of the Federal food and drugs act, specifically designating said act.

(*c*) If a particular guaranty in respect to any article or articles be given, it should be incorporated in or attached to the bill of sale, invoice, bill of lading, or other schedule, giving the name and quantity of the article or articles sold, and shall not appear on the label or package. A guaranty, if worded substantially according to the following form, will comply with all the requirements of the act:

"I (we), the undersigned, do hereby guarantee that the articles of food (or drugs) listed herein (or specifying the same) are not adulterated or misbranded within the meaning of the Federal food and drugs act.

"(Signature and address of guarantor.)"

(*d*) In lieu of a particular guaranty for each consignment, lot, or article of food or drugs, a general continuing guaranty may be furnished by the guarantor to actual or prospective purchasers. Such general guaranty shall conform to the requirements of paragraph *b* of this regulation.

(*e*) It having been determined that the legends "Guaranteed under the food and drugs act, June 30, 1906," and "Guaranteed by (name of guarantor), under the food and drugs act, June 30, 1906," borne on the labels or packages of foods and drugs, are each misleading and deceptive, in that the public is induced by such legends to believe that the articles to which they relate have been examined and approved by the Government and that the Government guarantees that they comply with the law, the use of either legend, or any similar legend, on labels or packages is prohibited.

(*f*) A dealer in food or drug products will not be liable to prosecution if he can establish that the articles were sold to him under a guaranty given in compliance with this regulation.

Regulation 7.—Publication

(Section 4)

(*a*) After judgment of the court in any proceeding under the act, notice shall be given by publication. Such notice shall include the finding of the court and may include the findings of the analyst and such explanatory statements of facts as the Secretary of Agriculture may deem appropriate.

(*b*) This publication may be made in the form of a circular, notice, or bulletin, as the Secretary of Agriculture may direct.

(*c*) If an appeal be taken from the judgment of the court before such publication, that fact shall appear.

Regulation 8.—Standards for Drugs

(Section 7, in the case of drugs)

(*a*) A drug sold under or by a name, or a synonym, recognized in the United States Pharmacopœia or National Formulary, unless labeled as prescribed by paragraph *b* of this regulation, shall conform to the standard of strength, quality, or purity for the article as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of investigation. An article shall not be deemed to conform to such standard of strength, quality, or purity unless it conforms in every respect to all the requirements and specifications of the United States Pharmacopœia or the National Formulary for the article.

(*b*) A drug sold under or by a name, or a synonym, recognized in the United States Pharmacopœia or the National Formulary which does not conform to the standard of strength, quality, or purity for the article as determined by the test laid down therein shall be labeled with a statement to the effect that the drug is not a United States Pharmacopœia or National Formulary article; in addition it shall be labeled with a statement showing its own actual strength, quality, or purity, or else with a clear and exact statement of the nature and extent of the deviation from the standard of strength, quality, or purity set out for such article in the United States Pharmacopœia or National Formulary.

Regulation 9.—Confectionery

(Section 7)

The term "food" includes articles used for confectionery. The provisions of the act relating to food, as well as the specific provisions relating to confectionery, apply to confectionery.

Regulation 10.—Powdered

(Section 7, paragraph fourth, in the case of food)

An article of food shall neither be covered with a powder nor reduced to a powder in such manner that damage or inferiority is concealed.

Regulation 11.—Poisonous or Deleterious Ingredients

(Section 7, paragraph fifth, in the case of food)

A poisonous or other deleterious ingredient shall not be added to an article of food in such quantity as may by any possibility render the article injurious to health. Any ingredient artificially introduced into an article of food is an added ingredient.

Regulation 12.—External Application of Preservatives

(Section 7, proviso of paragraph fifth, in the case of food)

A food to which a preservative is applied externally, in order to be within the proviso of section 7, paragraph fifth, must bear on the covering or package directions for the effective removal of such preservative.

Regulation 13.—Colors and Preservatives

(Section 7, in the case of food)

(*a*) Only harmless colors and harmless preservatives may be used in articles of food.

(*b*) A color, preservative, or other substance, even though harmless, shall not be used in the preparation of any article of food in a manner whereby damage or inferiority is concealed.

(*c*) The Secretary of Agriculture shall determine from time to time the wholesomeness of colors, preservatives, and other substances which are added to foods, and shall make public announcement in such manner as he may deem appropriate of the results of the investigations. When so published the results of the investigation shall serve as a guide in enforcing the act.

(*d*) The Secretary of Agriculture may authorize the certification of colors found by him to be in compliance with the law and these regulations.

Regulation 14.—Label

(Section 8)

(*a*) The term "label," as used in the act, includes any legend and descriptive matter or design appearing upon the article or its container, and also includes circulars, pamphlets, and the like which are packed and go with the article to the purchaser, and such letters, circulars, and pamphlets to which reference is made either on the label attached to the package or on the package itself.

(*b*) The label shall bear, plainly and conspicuously displayed, all the information specifically required by the act, e. g., the quantity of the contents of food in package form, in accordance with regulation 26, and the quantity or proportion of the drugs named in section 8 of the act, in accordance with regulations 24 and 25. The label shall also bear such other descriptive matter as the character of the product may require.

(*c*) A label in a foreign language shall conform to these regulations and shall bear all the information required by the act in English, as well as in each of the foreign languages used to describe the article of food or drugs.

(*d*) The label shall be free from any statement, design, or device regarding the article or the ingredients or substances contained therein, or quality thereof, or place of origin, which is false or misleading in any particular. The terms "design" and "device" include pictorial matter of every description, abbreviations, characters, and signs.

(*e*) A food or drug product shall not be labeled or branded in such a manner as to deceive or mislead the purchaser. Direct misstatements and indirect misrepresentations regarding the article or its ingredients by means of designs, printed testimonials, devices, or artifices in the arrangement, style, or dress of the package, or in the arrangement of the printed or pictorial matter in or upon the label or package are prohibited.

(*f*) An article containing more than one food product or active medicinal agent is misbranded if named after a single constituent. In the case of drugs the nomenclature employed by the United States Pharmacopœia and the National Formulary shall obtain.

(*g*) The statement of the formula is not required on the label except in so far as may be necessary to prevent adulteration or misbranding.

(*h*) An article so labeled as to convey the impression that all of its ingredients are declared is misbranded if the list of ingredients is incomplete.

Regulation 15.—When Label is Required

(Section 8)

The use of a label is not compulsory except in the following cases:

(*a*) Imitations (regulation 20, *a*).

(*b*) Foods and drugs containing the ingredients mentioned in section 8, paragraph second, in the case of drugs, and paragraph second, in the case of foods (regulations 24 and 25).

(*c*) Drugs which fall within the proviso of section 7, paragraph first, in the case of drugs (regulation 8, *b*).

(*d*) Foods in package form (regulation 26).

(*e*) Compounds and blends which are brought within the proviso of section 8, paragraph fourth, in the case of foods (regulations 19 and 20).

(*f*) Substitution (regulation 21).

(*g*) Foods which fall within the proviso of section 7, paragraph fifth, in the case of food (regulation 12).

(*h*) By-product or waste material (regulation 22).

(*i*) Articles intended for export which fall within the proviso of section 2 of the act (regulation 27, *b*).

(*j*) Articles which require specific labeling to avoid adulteration or misbranding.

Regulation 16.—Name and Address of Manufacturer

(Section 8)

(*a*) The name of the manufacturer or producer need not be given upon the label, but if given it must be the true name. The words "Packed for ———," "Distributed by ———," or some equivalent phrase, shall be added to the label in case the name which appears upon the label is not that of the actual manufacturer or producer.

(*b*) The place of manufacture or production need not be given upon the label except where, in order to avoid misbranding, it is necessary to indicate clearly that the article is of domestic and not foreign origin, and also in the case of mixtures and compounds sold under their own distinctive names (regulation 19), to bring the articles within the terms of the proviso of section 8, paragraph fourth, of the act.

(*c*) The place of manufacture or production, if given, must be correctly stated.

(*d*) When a person, firm, or corporation actually manufactures or produces a food or a drug in two or more places, the actual place of manufacture or production of each particular package need not be stated on the label except when the mention of any place, to the exclusion of the others, deceives or misleads.

Regulation 17.—Character of Name

(Section 8)

(*a*) A simple or unmixed food or drug product shall be sold by its common name in the English language; or, if a drug recognized in the United States Pharmacopœia or National Formulary, by the name or names therein designated.

(*b*) A geographical name indicating that a food or drug product was manufactured or produced in a specific place shall not be used unless such product was manufactured or produced in that place.

(*c*) A name which is distinctive of a product of a specific foreign country shall not be used upon an article not manufactured or produced in that country, except as an indication of the type or style of quality or manufacture, and then only when the product possesses substantially the characteristic qualities of the product of that foreign country. Such name shall be so qualified as to remove any impression that the article was manufactured or produced in the country in which the name is distinctive.

Regulation 18.—"Distinctive Name" and "Own Distinctive Name"

(Section 8)

(*a*) A "distinctive name" is a name that distinguishes one kind of food from another.

(*b*) The expression "own distinctive name" as used in section 8, paragraph fourth, means a name which is purely arbitrary or fanciful and distinguishes a particular article of food from all other articles of food. It shall not give a false indication of origin, character, composition, ingredients, or place of manufacture, and shall not lead the purchaser to suppose that the product is other than what it is.

Regulation 19.—Mixtures or Compounds with Distinctive Names

(Section 8, paragraph fourth, in the case of food, subparagraph first)

(*a*) The terms "mixtures" and "compounds" are interchangeable.

(*b*) Mixtures or compounds with distinctive names shall not be imitations of other articles, whether simple, mixed, or compound, or offered for sale under the names of other articles. In addition to the distinctive name, they shall bear on the same label or brand the name of the place of manufacture or production. If the name of the place be one which is found in different States, Territories, or countries, the name of the State, Territory, or country, as well as the name of the place, must be stated.

(*c*) An article of food is not within the terms of the proviso of section 8, paragraph fourth, subparagraph first, unless it is labeled in accordance with this regulation.

Regulation 20.—Imitations, Blends, Compounds without Distinctive Names

(Section 8, paragraph first, in the case of food, and paragraph fourth, in the case of food, subparagraph second)

(*a*) An imitation shall bear on the label the word "imitation," and, in addition, a clear statement of the principal or essential ingredients of the article.

(*b*) Compounds and blends, in order to be within section 8, paragraph fourth, in the case of food, subparagraph second, shall bear on the label the word "compound" or "blend," as the case may be, and, in addition, a clear statement of the principal or essential ingredients of the article.

Regulation 21.—Substitution

(Sections 7 and 8)

When a substance of a recognized quality commonly used in the preparation of a food product is replaced in whole or in part by another substance not injurious or deleterious to health, the name of the substitute shall appear upon the label.

Regulation 22.—By-product or Waste Food Material

(Sections 7 and 8)

A food which consists in whole or in part of sound by-product or waste food material, such as pieces, stems, trimmings, and the like, shall not be labeled with the unqualified name of the substance from which such material is derived.

Regulation 23.—Certain Adulterations not Corrected by Label

(Section 7)

Proper labeling alone will not remove an article from the operation of the law. Certain forms of adulteration, e. g., the addition of a poisonous or deleterious ingredient which may render the article injurious to health, can not be corrected by any form of labeling.

Regulation 24.—Substances Required to be Stated on the Label

(Section 8, paragraph second, in the case of drugs, and paragraph second, in the case of food)

(*a*) A drug is misbranded if it fails to bear a statement on the label of the quantity or proportion of alcohol of any kind, morphine, opium, heroine, cocaine, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, acetanilid, or any derivative or preparation of any such substances therein contained. Such statement shall be made in a plain and conspicuous manner.

(*b*) A food is misbranded if it fails to bear a statement on the label of the quantity or proportion of any morphine, opium, heroine, cocaine, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of any such substances therein contained. Such statement shall be made in a plain and conspicuous manner.

(*c*) The term "alcohol" without qualifications means ethyl alcohol. If any alcohol other than ethyl alcohol be present in a drug the kind must be stated on the label. No statement is required of the presence of alcohol in foods.

(*d*) In declaring the quantity or proportion of any of the substances specified in paragraphs *a* and *b* of this regulation, the names by which they are designated in the act shall be used. In declaring the quantity or proportion of derivatives of any of the specified substances, in addition to the trade name of the derivative, the name of the specified substance shall also be stated so as to indicate clearly that the product is a derivative of the particular specified substance.

Regulation 25.—Method of Stating Quantity or Proportion

(Section 8)

(*a*) The quantity of alcohol in a drug shall be stated in terms of the average percentage by volume of absolute alcohol in the finished product.

(*b*) In a liquid the quantity of any substance specified in regulation 24, except alcohol, and the quantity of any derivative or preparation of any such substance, including derivatives of alcohol, shall be stated in terms of grains or minims per fluid ounce; in a solid, the quantity shall be stated in terms of grains or minims per avoirdupois ounce, provided that statements may be in terms of the metric system, if preferred.

(*c*) When two or more pills, wafers, tablets, powders, capsules, and the like are put up for sale or distribution in the same container, the quantity of the specified substance or derivative present in each pill, wafer, tablet, powder, capsule, or other unit shall be stated.

(*d*) A statement of the maximum quantity or proportion of any substance specified in regulation 24 present will meet the requirements, provided the maximum stated does not vary materially from the average quantity or proportion.

Regulation 26.—Statement of Weight, Measure, or Count

(Section 8, paragraph third, in the case of food)

(*a*) Except as otherwise provided by this regulation, a package of food shall be plainly and conspicuously marked with the quantity of the contents in terms of weight, measure, or numerical count on the outside of the container, or of the covering of the package usually delivered to the consumer.

(*b*) The quantity of the contents so marked shall be the quantity of food in the package.

(*c*) The statement of the quantity of the contents shall be plain and conspicuous, shall not be a part of or obscured by any legend or design, and shall be so placed and in such characters as to be readily seen and clearly legible when the size of the package and the circumstances under which it is ordinarily examined by purchasers or consumers are taken into consideration.

(*d*) The quantity of the contents when stated by weight or measure shall be marked in terms of the largest unit contained in the package, except that, in the case of an article with respect to which there exists a definite trade custom for marking the quantity of the article in terms of fractional parts of larger units, it may be so marked in accordance with the custom. Common fractions shall be reduced to their lowest terms; fractions expressed as decimals shall be preceded by zero and shall be carried out to not more than two places.

(*e*) Statement of weight shall be in terms of the avoirdupois pound and ounce; statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and its customary subdivisions, i. e., gallons, quarts, pints, or fluid ounces, and shall express the volume of the liquid at 68° F. (20° C.); statement of dry measure shall be in terms of the United States standard bushel of 2,150.42 cubic inches and its customary subdivisions, i. e., bushels, pecks, quarts, or pints, or, in the case of articles in barrels, in terms of the United States standard barrel and its lawful subdivisions, i. e., third, half, or three-quarters barrel, as fixed by the act of March 4, 1915 (38 Stat. 1186): *Provided*, That statement of quantity may be in terms of metric weight or measure. Statement of metric weight shall be in terms of kilograms or grams. Statement of metric measure shall be in terms of liters or cubic centimeters. Other terms of metric weight or measure may be used if it appears that a definite trade custom exists for marking articles with such other terms and the articles are marked in accordance with the custom.

(*f*) The quantity of solids shall be stated in terms of weight and the quantity of liquids in terms of measure, except that in case of an article in respect to which there exists a definite trade custom otherwise the statement may be in terms of weight or measure in accordance with such custom. The quantity of viscous or semisolid foods or of mixtures of solids and liquids may be stated either by weight or measure, but the statement shall be definite and shall indicate whether the quantity is expressed in terms of weight or measure, as, for example, "weight 12 oz." or "12 oz. avoirdupois," "volume 12 ounces" or "12 fluid ounces."

(*g*) The quantity of the contents shall be stated in terms of weight or measure unless the package is marked by numerical count and such numerical count gives accurate information as to the quantity of the food in the package.

(*h*) The quantity of the contents may be stated in terms of minimum weight, minimum measure, or minimum count, for example, "minimum weight 10 oz.," "minimum volume 1 gallon," or "not less than 4 fl. oz.," but in such case the statement must approximate the actual quantity and there shall be no tolerance below the stated minimum.

(*i*) The following tolerances and variations from the quantity of the contents marked on the package shall be allowed:

(1) Discrepancies due exclusively to errors in weighing, measuring, or counting which occur in packing conducted in compliance with good commercial practice.

(2) Disrepancies due exclusively to differences in the capacity of bottles and similar containers, resulting solely from unavoidable difficulties in manufacturing such bottles or containers so as to be of uniform capacity: *Provided*, That no greater tolerance shall be allowed in case of bottles or similar containers which, because of their design, can not be made of approximately uniform capacity than is allowed in case of bottles or similar containers which can be manufactured so as to be of approximately uniform capacity.

(3) Discrepancies in weight or measure due exclusively to differences in atmospheric conditions in various places and which unavoidably result from

the ordinary and customary exposure of the packages to evaporation or to the absorption of water.

Discrepancies under classes (1) and (2) of this paragraph shall be as often above as below the marked quantity. The reasonableness of discrepancies under class (3) of this paragraph will be determined on the facts in each case.

(*j*) A package containing one-half avoirdupois ounce of food or less is "small" and shall be exempt from marking in terms of weight.

(*k*) A package containing one fluid ounce of food or less is "small" and shall be exempt from marking in terms of measure.

(*l*) When a package is not required by paragraph *g* to be marked in terms of either weight or measure and the units of food therein are six or less, it shall, for the purpose of this regulation, be deemed "small" and shall be exempt from marking in terms of numerical count.

Regulation 27.—Articles Intended for Export

(Section 2)

(*a*) An article of food or drugs intended for export is not adulterated or misbranded within the meaning of the act if it is established by the shipper or exporter that the article is prepared or packed according to the specifications or directions of the foreign purchaser and that no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which the article is intended to be shipped.

(*b*) An article intended for export prepared or packed in accordance with paragraph *a* of this regulation shall be labeled on the outside container or wrapper so as to show that the article is intended for export and is prepared or packed in accordance with the specifications or directions of the foreign purchaser. This marking is required only on an article which otherwise would be classed as adulterated or misbranded.

(*c*) An article prepared for export in accordance with paragraphs *a* and *b* of this regulation if sold or offered for sale for domestic consumption is subject to all the provisions of the act regarding domestic sale.

Regulation 28.—Declaration on Imports

(Section 11)

(*a*) All invoices of food or drug products shipped to the United States shall have attached to them a declaration of the shipper, executed before a United States consular officer, as follows:

FORM NO. 198—CONSULAR

(Corrected July, 1916)

DECLARATION OF SHIPPER OF FOOD AND DRUG PRODUCTS

Regarding shipment covered by Invoice No. ____, certified at----------, ----------, on----------, 19--.

I, the undersigned, am the ----------
(Seller or owner, or agent of seller or owner)
of the merchandise mentioned and described in the accompanying consular invoice. It consists of food or drug products which contain no added substances injurious to health. These products were grown in ---------- and manufactured in --------
(Country)
---------- by ---------- during the year ------, and
(Town and country) (Name of manufacturer)
are exported from ---------- and consigned to ----------. They bear no false labels or
(City) (City)
marks, contain no added coloring matter except ----------,
(State coloring matter used, if any)
no preservative (salt, sugar, vinegar, or wood smoke excepted) except ----------
---------- and are not of a character to cause prohibi-
(State preservatives used, if any)
tion or restriction in sale in the country where made or from which exported, nor do I believe that they are of such a character as to prohibit their entry into the United States, in accordance with the provisions of the Federal food and drugs act.

I do solemnly and truly declare the foregoing statements to be true, to the best of my knowledge and belief.

Dated at ---------- this ---------- day of ----------, 19--.
(Place) (Date)
(Signature) ----------

INSTRUCTIONS TO CONSULAR OFFICERS

1. This declaration is to be firmly attached to the extra copy of consular invoice on Form No. 138–140 or 139–140 of shipment over $100 in value.
2. The official seal must be firmly impressed on the declaration, and the number, date of certification of invoice, and name of post plainly indicated.
3. Shipper should be instructed to declare the name of the manufacturer whenever possible.
4. If the declaration is believed to be incorrect or incomplete, or if consul believes that the goods are liable to detention, he should note such information on the invoice in the consular corrections or remarks column.

(*b*) In case of importations to be entered at Baltimore, Boston, Buffalo, Chicago, Cincinnati, Denver, Kansas City, Minneapolis, New Orleans, New York, Philadelphia, San Francisco, San Juan, Porto Rico, Savannah, St. Louis, Seattle, and other points where food and drug inspection stations shall be established, this declaration shall be attached to the invoice on which entry is made. In other cases the declaration shall be attached to a copy of the invoice prepared for the Food and Drug Administration.

Regulation 29.—Import Procedure

(Section 11)

(*a*) The enforcement of the provisions of the Federal food and drugs act as they relate to imported foods and drugs will, as a general rule, be under the local direction of the officers of the stations of the Food and Drug Administration, Department of Agriculture, collectors of customs acting as administrative officers in carrying out directions relative to the detention, exportation, and destruction of merchandise and action under the bond in case of noncompliance with the provisions of the act.

(*b*) Merchandise subject to examination in accordance with the provisions of the act shall not be delivered to the consignee prior to report of examination, unless a bond has been given on the appropriate form for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal of the consignee to return such goods for any cause to the custody of the collector when demanded, for the purpose of excluding them from the country or for any other purpose, said consignee shall forfeit the full amount of the bond.

(*c*) As soon as the importer makes entry, the invoices covering foods and drugs and the public stores packages shall be made available, with the least possible delay, for inspection by the representative of the station. When no sample is desired the invoice shall be stamped by the station "No sample desired. Food and Drug Administration, U. S. Department of Agriculture, per (initials of inspecting officer)."

(*d*) On the same day that samples are requested by the station the collector or appraiser shall notify the importer that samples will be taken, that the goods must be held intact pending a notice of the result of inspection and analysis, and that in case the goods do not comply with the requirements of the Federal food and drugs act they must be returned to the collector for disposition. This notification may be given by the collector or appraiser through individual notices to the importer or by suitable bulletin notices posted daily in the customhouse.

(*e*) NO VIOLATION—RELEASE:

As soon as examination of the samples is completed, if no violation of the act is detected, the chief of the station shall send a notice of release to the importer, a copy of this notice to be sent to the collector of customs for his information.

(*f*) VIOLATION:

(1) If a violation of the food and drugs act is disclosed, the chief of the station shall send to the importer due notice of the nature of the violation and of the time and place where evidence may be presented showing that the goods should not be refused admission. At the same time similar notice regarding detention of the goods shall be sent to the collector, requesting him to refuse delivery of the goods or to require their return to customs custody if by any chance the merchandise was released without the bond referred to in paragraph *b* of this regulation being given. The time allowed the importer

for representations regarding the shipment may be extended at his request for a reasonable period to permit him to secure such evidence.

(2) If the importer does not reply to the notice of hearing in person or by letter within the time allowed on the notice, a second notice, marked "second and last notice," shall be sent at once by the chief of the station, advising him that failure to reply will cause definite recommendation to the collector that goods be refused entry.

Rejected goods.

(3) In all cases where the goods are to be refused entry, the chief of the station within one day after hearing, or if the importer does not appear or reply within three days after second notice, shall notify the collector in duplicate accordingly.

(4) Not later than one day after receipt of this notice the collector shall sign and transmit to the importer one of the copies, which shall serve as notification to the importer that the goods must be exported or destroyed within three months from such date, as provided by law; the other notice shall be retained as office record and later returned as a report to chief of station. In all cases the importer shall return his notice to the collector, properly certified as to the information required, as the form provides.

Goods to be conditioned.

(5) If goods may be released after relabeling or after certain conditions are complied with, a notice shall be sent by the chief of station direct to the importer, a carbon copy being sent to the collector. This notice must state specifically the conditions to be performed, so as to bring the performance thereof under the provisions of the customs bonds on consumption and warehouse entries, these bonds including provisions requiring compliance with all of the requirements of the food and drugs act and all regulations and instructions issued thereunder. The notice will also state the officer to be notified by the importer when the goods are ready for inspection.

(6) The importer must return the notice to the collector or chief of station, as designated, with the certificate thereon filled out, stating that he has complied with the prescribed conditions and that the goods are ready for inspection at the place named.

(7) This notice will be delivered to the inspection officer, who, after inspection, will indorse the result thereof on the back of the notice and return the same to the collector or to the chief of the station, as the case may be.

(8) When the conditions to be complied with are under the supervision of the chief of the station, and these conditions have been fully met, he shall release the goods to the importer, sending a copy of the notice of release to the collector for his information.

When, however, release is still conditioned upon destruction of rejections or of some portion of the shipment or the importer has been unsuccessful in meeting the conditions imposed, and the goods must be exported or destroyed, the chief of station shall immediately give notice in duplicate to the collector of the results of inspection. The collector shall sign and immediately transmit one copy of the notice to the importer and proceed in the usual manner.

(9) If the goods are detained, subject to conditioning to be performed under the collector's supervision, the collector, as soon as conditions are performed, will notify the importer that the goods are released. If goods are not properly conditioned within the period allowed, the goods must be exported or destroyed.

(10) When final action has been taken on goods which have been refused entry or on goods the release of which is subject to conditions to be performed under the collector's supervision, the collector shall send to the chief of station a notice of such final action, giving the date of release or destruction or date of export and country to which exported.

(11) When intent to violate the act is evident, the privilege of relabeling, cleaning, and similar renovation will not be allowed. Similarly at the discretion of the station chief this privilege will not be allowed in those cases where through carelessness or otherwise shipments in violation of the act are offered for entry when the exporter or importer has been informed in connection with violations in previous shipments. In general, when shipments with identical labeling have been detained for relabeling three times, the privilege of relabeling will not be extended.

(12) When the privilege of sorting or renovating shipments is allowed, the importer must furnish satisfactory evidence as to the identity of the goods before release is given. This privilege shall not be granted except as stated conditions agreed to by the importer include segregation of goods at a stated place and apart from other goods of similar nature.

(13) The chief of station or other officer by him appointed when it is deemed advisable may require of the importer an affidavit as evidence that the goods have been properly disposed of, such affidavit to be executed before a notary public or other officer authorized to administer oaths generally.

(14) When imported merchandise subject to the provisions of the Federal food and drugs act is shipped to another port for reconditioning or exportation, the goods must be shipped under customs carrier's manifest, in the same manner as shipments in bond.

(15) Collectors of customs will perform the inspection service whenever goods are to be exported or destroyed, and in other cases when there is no officer of the station available.

(16) Collectors of customs and representatives of the station will confer and arrange the apportionment of the inspection service according to local conditions. Officers of the station will, whenever feasible, perform the inspection service when cleaning, bringing up to standard, and like reconditioning operations are involved.

(*g*) PENALTIES:

(1) In case of failure to comply with the instructions or recommendations of the chief of the station as to the conditions under which the merchandise may be disposed of, the collector shall notify the chief of the station in all cases coming to his attention within three days after inspection or after the expiration of the three months allowed by law if no action is taken.

(2) The chief of the station, upon receipt of the above described notice, and in all cases of failure to meet the conditions imposed in order to comply with the provisions of the Federal food and drugs act coming directly under his supervision, shall transmit to the collector of customs such evidence as he may have at hand tending to indicate the importer's liability and make a recommendation accordingly.

(3) The collector, within three days of the receipt of this recommendation, whether favorable or otherwise, shall notify the importer that, the legal period of three months for exportation or destruction having expired, action will be taken within 30 days to enforce the terms of the bond, unless, in the meantime, application for remission or mitigation of penalties incurred, with definite offer of settlement, is filed with the collector. The application should be in duplicate, with a full statement of reasons, under oath.

(4) The collector shall transmit the application in duplicate, together with his own and the station chief's recommendation, both in duplicate, to the Secretary of the Treasury, Division of Customs, for his action.

(*h*) NONLABORATORY PORTS:

(1) At ports of entry where there is no station of the Food and Drug Administration, the collector or deputy, on the day when the first notice of expected shipment of foods or drugs is received, either by invoice or entry, shall notify the chief of the station in whose territory the port is located.

(2) On the day of receipt of such notice the station chief shall mail to the collector appropriate notice, if no sample is desired. This notice serves as an equivalent to stamping the invoices at station ports with the legend "No samples desired. Food and Drug Administration, U. S. Department of Agriculture, per (initials of inspecting officer)."

(3) If samples are desired, the station chief shall immediately notify the collector.

(4) The collector at once shall forward samples, accompanied by description of shipment.

(5) When samples will be requested from each shipment of certain foods or drugs, the chief of station shall furnish to collector and deputies at ports within the station's territory a list of such products, indicating size of sample necessary. Samples should then be sent promptly on arrival of goods without awaiting special request.

(6) In all other particulars the procedure shall be the same at nonlaboratory ports as at laboratory ports, except that the time consumed in delivery of notices by mail shall be allowed for.

(*i*) The station chief shall be deemed a customs officer in enforcing import regulations

Regulation 30.—Articles Suitable Only for Technical or Restricted Use, Denaturing

(Section 11)

(*a*) A food or drug which is adulterated or misbranded within the meaning of this act and which is offered for import for industrial purposes must be denatured and the invoice thereof must bear a statement showing that the article is to be used for industrial purposes.

Where, however, it is impracticable to denature such article it may be permitted entry provided—

(1) It is plainly and conspicuously labeled, in the case of food, "inedible," and, in the case of drugs, "not for medicinal use."

(2) At the time of entry the importer submits a statement in writing that the article will not be used as a food or drug.

(3) At the time of entry the importer submits a statement that the article will be used in a certain suitable manner by a certain named party or parties.

(4) At the time of entry the importer agrees to furnish satisfactory proof as to the actual use of the article and the name or names of the parties who use it.

The penal bond given at the time of entry will not be canceled until such evidence of satisfactory disposition shall have been received.

(*b*) A food or drug having but a restricted legitimate use and of such character that it can not legally be distributed for unrestricted general use, e. g., pharmacopœial crude drugs deficient in active principle and certain substitutes for pharmacopœial crude drugs, may be allowed entry if properly labeled, provided suitable evidence be furnished by affidavit or otherwise that it will be used by a designated party or parties for manufacture into articles in which it may be legitimately employed. The penal bond given at the time of entry will not be canceled until proof of satisfactory use of the product shall have been received.

Regulation 31.—Alterations and Amendments of Regulations

These regulations may be altered or amended at any time without previous notice, with the concurrence of the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce.

The foregoing rules and regulations are hereby adopted, effective on this date, and all previous regulations for the enforcement of the Federal food and drugs act are hereby rescinded.

A. W. Mellon,
Secretary of the Treasury.
Arthur M. Hyde,
Secretary of Agriculture.
R. P. Lamont,
Secretary of Commerce.

Washington, D. C., *October 31, 1930.*

THE FOOD AND DRUGS ACT, JUNE 30, 1906, AS AMENDED AUGUST 23, 1912, MARCH 3, 1913, MARCH 4, 1913, JULY 24, 1919, JANUARY 18, 1927, AND JULY 8, 1930

AN ACT For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That it shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food or drug which is adulterated or misbranded, within the meaning of this act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than one thousand dollars or sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court.

SEC. 2. That the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food or drugs which is adulterated or misbranded, within the meaning of this act, is hereby prohibited; and any person who shall ship or deliver for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to a foreign country, or who shall receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in original unbroken packages, for pay or otherwise, or offer to deliver to any other person, any such articles so adulterated or misbranded within the meaning of this act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods or drugs, or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor, and for such offense be fined not exceeding two hundred dollars for the first offense, and upon conviction for each subsequent offense not exceeding three hundred dollars or be imprisoned not exceeding one year, or both, in the discretion of the court: *Provided*, That no article shall be deemed misbranded or adulterated within the provisions of this act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this act.

SEC. 3. That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor[1] shall make uniform rules and regulations for carrying out the provisions of this act, including the collection and examination of specimens of foods and drugs manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country.

SEC. 4. That the examinations of specimens of foods and drugs shall be made in the Bureau of Chemistry[2] of the Department of Agriculture, or under the direction and supervision of such bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this

[1] Secretary of Commerce (37 Stat. 736).
[2] Food and Drug Administration (H. R. 7491, May 27, 1930).

act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this act have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid.

SEC. 5. That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

SEC. 6. That the term "drug," as used in this act, shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food," as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound.

SEC. 7. That for the purposes of this act an article shall be deemed to be adulterated:

In case of drugs:

First. If, when a drug is sold under or by a name recognized in the United States Pharmacopœia or National Formulary, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of investigation: *Provided*, That no drug defined in the United States Pharmacopœia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof, although the standard may differ from that determined by the test laid down in the United States Pharmacopœia or National Formulary.

Second. If its strength or purity fall below the professed standard or quality under which it is sold.

In the case of confectionery:

If it contain terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt, or spirituous liquor or compound or narcotic drug.

In the case of food:

First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.

Second. If any substance has been substituted wholly or in part for the article.

Third. If any valuable constituent of the article has been wholly or in part abstracted.

Fourth. If it be mixed, colored, powdered, coated, or stained in a manner whereby damage or inferiority is concealed.

Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health: *Provided*, That when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by maceration in water, or otherwise, and directions for the removal of said preservative shall be printed on the covering or the package, the provisions of this act shall be construed as applying only when said products are ready for consumption.

Sixth. If it consist in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter.

SEC. 8. That the term "misbranded," as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product

which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

That for the purposes of this act an article shall also be deemed to be misbranded:

In case of drugs:

First. If it be an imitation of or offered for sale under the name of another article.

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroine, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of any such substances contained therein.

Third. If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.

In the case of food:

First. If it be an imitation of or offered for sale under the distinctive name of another article.

Second. If it be labeled or branded so as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package, or if it fail to bear a statement on the label of the quantity or proportion of any morphine, opium, cocaine, heroine, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of any such substances contained therein.

Third. If in package form, the quantity of the contents be not plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count: *Provided, however,* That reasonable variations shall be permitted, and tolerances and also exemptions as to small packages shall be established by rules and regulations made in accordance with the provisions of section three of this act.[3]

Fourth. If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular: *Provided,* That an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases:

First. In the case of mixtures or compounds which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article, if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced.

Second. In the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds, imitations, or blends, and the word "compound," "imitation," or "blend," as the case may be, is plainly stated on the package in which it is offered for sale: *Provided,* That the term blend as used herein shall be construed to mean a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only: *And provided further,* That nothing in this act shall be construed as requiring or compelling proprietors or manufacturers of proprietary foods which contain no unwholesome added ingredient to disclose their trade formulas, except in so far as the provisions of this act may require to secure freedom from adulteration or misbranding.

Fifth. If it be canned food and falls below the standard of quality, condition, and/or fill of container, promulgated by the Secretary of Agriculture for such canned food and its package or label does not bear a plain and conspicuous statement prescribed by the Secretary of Agriculture indicating that such canned food falls below such standard. For the purposes of this paragraph the words canned food mean all food which is in hermetically sealed containers and

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[3] This section has been amended (Kenyon amendment, 41 Stat. 271) as follows: That the word "package" where it occurs the second and last time in the act entitled "An act to amend section 8 of an act entitled 'An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes,'" approved March 3, 1913, shall include and shall be construed to include wrapped meats inclosed in papers or other materials as prepared by the manufacturers thereof for sale.

is sterilized by heat, except meat and meat food products which are subject to the provisions of the meat inspection act of March 4, 1907 (Thirty-fourth Statutes, page 1260), as amended, and except canned milk; the word class means and is limited to a generic product for which a standard is to be established and does not mean a grade, variety, or species of a generic product. The Secretary of Agriculture is authorized to determine, establish, and promulgate, from time to time, a reasonable standard of quality, condition, and/or fill of container for each class of canned food as will, in his judgment, promote honesty and fair dealing in the interest of the consumer; and he is authorized to alter or modify such standard from time to time as, in his judgment, honesty and fair dealing in the interest of the consumer may require. The Secretary of Agriculture is further authorized to prescribe and promulgate from time to time the form of statement which must appear in a plain and conspicuous manner on each package or label of canned food which falls below the standard promulgated by him, and which will indicate that such canned food falls below such standard, and he is authorized to alter or modify such form of statement, from time to time, as in his judgment may be necessary. In promulgating such standards and forms of statements and any alteration or modification thereof, the Secretary of Agriculture shall specify the date or dates when such standards shall become effective, or after which such statements shall be used, and shall give public notice not less than ninety days in advance of the date or dates on which such standards shall become effective or such statements shall be used. Nothing in this paragraph shall be construed to authorize the manufacture, sale, shipment, or transportation of adulterated or misbranded foods.

SEC. 9. That no dealer shall be prosecuted under the provisions of this act when he can establish a guaranty signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, from whom he purchases such articles, to the effect that the same is not adulterated or misbranded within the meaning of this act, designating it. Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles to such dealer, and in such case said party or parties shall be amenable to the prosecutions, fines, and other penalties which would attach, in due course, to the dealer under the provisions of this act.

SEC. 10. That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this act, and is being transported from one State, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this act or the laws of that jurisdiction: *Provided, however*, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except, that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

SEC. 11. The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of foods and drugs which are being imported into the United States or offered for import, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture, and have the right to introduce testimony, and if it appear from the examination of such samples that any article of food or drug offered to be imported into the United States is adulterated or misbranded within the meaning of this act, or is otherwise dangerous to the health of the people of the United States, or is of a kind forbidden entry into, or forbidden to be sold or

restricted in sale in the country in which it is made or from which it is exported or is otherwise falsely labeled in any respect, the said article shall be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any goods refused delivery which shall not be exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee such goods pending examination and decision in the matter on execution of a penal bond for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal to return such goods for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of the bond: *And provided further*, That all charges for storage, cartage, and labor on goods which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

SEC. 12. That the term "Territory" as used in this act shall include the insular possessions of the United States. The word "person" as used in this act shall be construed to import both the plural and the singular, as the case demands, and shall include corporations, companies, societies, and associations. When construing and enforcing the provisions of this act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person.

SEC. 13. That this act shall be in force and effect from and after the first day of January, nineteen hundred and seven.

Approved June 30, 1906.

U. S. GOVERNMENT PRINTING OFFICE: 1930